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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,889	01/13/2004	Steven G. Nadler	D0284 NP	1732

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,889

Applicant(s)

NADLER ET AL.

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/04, 9/05&3/06</u> | 6) <input checked="" type="checkbox"/> Other: <u>see attachment 1</u> . |

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Applicant's response to restriction filed 2/6/2006 is acknowledged. According to applicant claims 1-20 are canceled. However, the examiner could not find claims 19-20 anywhere in the application. **Therefore claim 21 has been renumbered according to Rule 26 and from now will be referred to as claim 19.**

DETAILED ACTION

Claim 19 is under examination on the merits. Claims 1-18 are canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase " NFkB pathway" is indefinite. Applicant has not defined said pathway in terms of all its members in the specification. According to prior art NFkB is involved in numerous events (pathways) such as apoptosis, transcription etc., in a cell and many members of said pathways are still unknown. It is totally unclear as which proteins and/or enzymes applicant is referring to. Appropriate clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Dalla-Favera et al. (WO 00/00185, issued Jan 2000). Dalla-Favera in page 4, teaches methods of phosphorylating BCL-6 protein (polypeptide) having 100% identity to SEQ ID NO:18 of this invention (see attached sequence alignment) wherein said phosphorylation results in decreasing the activity of said BCL-6 protein. Its BCL-6 protein is inherently a member of NFkB pathway, activating claim 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. patent No. 6,140,125 issued 10/2000) in view of current protein (polypeptide) modulation techniques.

Taylor teaches a polypeptide having 100% identity to BCL-6 polypeptide of this invention (see the attached sequence alignment) . Said BCL-6 polypeptide is inherently a member of "NFkB pathway". Taylor also teaches (see column 2) methods for reducing (inhibiting) expression of its BCL-6 encoding gene (see abstract). Taylor does not specifically teach methods of inhibiting the polypeptide expressed by BCL-6 gene.

Current polypeptide modulation techniques teach that once the expression product of a useful gene (in this case BCL-6 encoding gene) is identified it is common

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practice to try to identify modulators (including inhibitors) of said polypeptide according to current polypeptide modulation techniques.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with BCL-6 polypeptide of Taylor and treat it with a variety of modulators in order to find agents which inhibit its activity, according to current polypeptide modulation techniques. One of ordinary skill in the art is motivated in inhibiting the activity of said BCL-6 polypeptide because Taylor teaches that BCL-6 polypeptides are highly and uncontrollably expressed in several lymphomas (see column 2) and therefore, identification of BCL-6 inhibitors leads to production of anti-cancer drugs, rendering the invention obvious.

Finally one of skill in the art has a reasonable expectation of success in inhibiting BCL-6 polypeptides both in vivo and in vitro because methods of inhibiting polypeptides with modulators are well established in the prior.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Maryam Monshipouri Ph.D.

Primary Examiner
